

Attorney Docket No. 0229

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Application of: Lawrence R. Koh for Reissue of

U. S. Patent No.: 6,015,397 Issued Jan. 18, 2000

For: NEEDLE POINT GUARD SAFETY CAP ASSEMBLY

Assistant Commissioner for Patents

and Trademarks

Washington, D. C. 20231

PROPOSED AMENDMENT

Pursuant to the filing herewith of Application for Reissue of the above-entitled patent, please enter the following preliminary amendments:

In the Claims:

Please add the following new claims:

1 23. (New) A needle point guard assembly attachable to a base of a syringe having a  
2 needle to allow said needle initially to protrude into an operative position for use, said  
3 assembly also being extensible into a locked position in which the needle point is fully  
4 protected, comprising:  
5 (a) a syringe attachment member operable to attach the said needle point guard  
6 assembly to the needle hub of a syringe;

7 (b) an extensible frame having a proximal end segment hingedly secured to said  
8 syringe attachment member and a distal end segment hingedly connected to said  
9 proximal end segment;

10 (c) an elongate needle point cover member being open at one end, and the opposite  
11 end thereof having an end wall with a hole through which the needle when operative  
12 will extend, said end wall also having a needle point receiving well that is laterally  
13 displaced from said hole;

14 (d) said cover member at said open end, and on one side thereof, being hingedly  
15 secured to the distal end of said distal end segment;

16 (e) a lid member hingedly secured to said open end of said cover member and having  
17 a hole through which the needle may pass, but normally closing said open end of said  
18 cover member, but wherein the needle may pass through both the hole in the end wall

19 and the hole in the lid member when extended for use;  
20 (f) said extensible frame being manually actuatable by a single hand of an operator so  
21 as to be extended sufficiently to pass through the hole in the lid member, remaining  
22 within the cover member, but not protruding through the hole in the cover member;  
23 (g) the cover member and hinged attachment to said extensible frame being integrally  
24 formed of a plastic material such that when the distal end of the needle no longer  
25 protrudes through the cover member hole, a rotational movement of said hinged  
26 attachment causing the needle point to move laterally into the cover member well.

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24. (New) A needle point guard assembly as in claim 23 wherein said well in said end wall of said cover member lies in that side of said cover member that is opposite to the hinged connection of the cover member to said extensible frame.

25. (New) A needle point guard assembly as in claim 23 wherein the entirety of said needle point guard assembly is integrally formed of a plastic material.

26. (New) A needle point guard assembly as in claim 23 further comprising a fulcrum on said needle point cover, said extensible frame being further operable when said end wall of said cover member lies beyond the extremity of the needle point to act on said fulcrum and thereby cause said cover member to rotate such that the sharp end of the needle enters into said cover member well.

27. (New) A needle point guard assembly as in claim 23 wherein the proximal end of said extensible frame comprises a base cup for attachment to a syringe and a wishbone segment having two arms and a base, said arms being flexibly attached to said base cup such that said base cup can rotate about the axis formed by the attachment of said arms to said wishbone connection.

1        28. (New) A needle-protected hypodermic syringe comprising:

2            a hypodermic syringe having at one end a base adapted to accept a needle point  
3            guard safety cap assembly;  
4            a hypodermic needle passing axially through said base;  
5            a needle point guard safety cap assembly proximally disposed on said base; and  
6            a hollow protective sheath having an open end and a closed end, removably disposed  
7            over a distal portion of said hypodermic needle, wherein said distal end of said  
8            hypodermic needle is disposed within said protective sheath near to said closed end.

29. (New) The needle-protected hypodermic syringe of claim 28 wherein said needle point guard safety cap assembly further comprises an extensible frame having proximal and distal end segments, one end of said proximal end segment being hingedly attached to said base and a second end of said proximal end segment being hingedly attached to one end of said distal end segment, a second end of said distal end segment being hingedly attached to a needle point cover member.

1 30. (New) The needle-protected hypodermic syringe of claim 29 wherein said proximal  
2 end segment further comprises a base cup adapted for connection to a hub of a  
3 hypodermic needle, said base cup being hingedly attached to said proximal end segment  
4 in such manner that a central axis of said base cup ordinarily lies near to a right angle  
5 from a central axis of said proximal end segment, whereby said proximal end segment will  
6 lie near to a right angle from said hypodermic needle, but can be rotated into a disposition  
7 that is colinear with said hypodermic needle by virtue of said hinged attachment between  
8 said base cup and said proximal end segment.

1 31. (New) The needle-protected hypodermic syringe of claim 29 wherein said hinged  
2 attachment of said needle point cover member is structured such that a central axis of said  
3 needle point cover member ordinarily lies near to a right angle from a central axis of said  
4 distal end segment, whereby, when said distal end segment is disposed to be essentially  
5 colinear with said proximal end segment, said needle point cover member will lie  
6 essentially at a right angle from said hypodermic needle, but can be rotated into a  
7 disposition that is colinear with said hypodermic needle by virtue of said hinged  
8 attachment between said distal end segment and said needle point cover member.

1 32. (New) A needle point guard safety cap assembly, comprising:  
2 a flexible frame comprising a proximal end segment that is hingedly attachable at a  
3 first end thereof to a hypodermic syringe having a colinear hypodermic needle,  
4 said flexible frame further comprising a distal end segment hingedly attached at a first  
5 end thereof to a second end of said proximal end segment; and  
6 a needle point cover member hingedly attached to a second end of said distal end  
7 segment, each of said proximal end segment, distal end segment, and needle point  
8 cover member being adapted to be rotationally placed into near colinear alignment  
9 with said hypodermic needle, whereby said needle point cover member can be placed  
10 into a protective, covering position over said needle tip by rotational means involving  
11 no inwardly directed in line movement of the fingers along the needle axis in the  
12 direction of said needle tip.

1 33. (New) A method of assembling a needle-protective hypodermic syringe, comprising:  
2 providing a syringe attachment member adapted for connection to a hub of a  
3 hypodermic syringe having a hypodermic needle disposed thereon;  
4 further providing a flexible frame flexibly attached at a first end thereof to said  
5 syringe attachment member wherein, in a relaxed condition, said flexible frame  
6 lies at an angle near to 90 degrees to a central axis of said syringe attachment  
7 member;  
8 further providing a needle point cover member flexibly attached to a second end  
9 of said flexible frame wherein, in a relaxed condition, said needle point cover  
10 member lies at an angle near to 90 degrees to a central axis of said flexible  
11 frame;  
12 connecting said syringe attachment member to said hub;  
13 rotating said flexible frame into linear alignment with said hub;  
14 passing said hypodermic needle at least partly into said flexible frame;  
15 rotating said needle point cover member into linear alignment with said flexible  
16 frame; and  
17 passing said hypodermic needle to full extent through said flexible frame,  
18 whereby the tip of said hypodermic needle lies within and near to a distal end of  
19 said needle point cover member.

1           34. (new) A protective cover assembly for a hypodermic needle  
2        having a needle base, a needle shaft, and a needle tip, the  
3        protective assembly comprising:

4           an elongated needle tip cover having an end wall with an  
5        opening through and beyond which the needle shaft can extend,  
6        either when the hypodermic needle is being stored prior to use or  
7        when the needle tip is exposed for use and the needle tip cover has  
8        therefore assumed a retracted position;

9           a collapsible frame coupled between the needle base and the  
10      needle tip cover to allow the needle tip cover to assume its  
11      retracted position, the frame also being extendible after the  
12      needle has been used to slide the needle tip cover along the needle  
13      until it protrudes beyond the needle tip;

14           means responsive to the extension of the frame for twisting  
15      the needle tip cover into a position in which the needle tip is  
16      protected by the end wall of the needle tip cover but is precluded  
17      from re-emerging through the opening therein; and

18           means responsive to the extension of the frame not only for  
19      locking the needle tip cover in the needle-protective position but  
20      also for locking the frame in its thus extended position.

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22           35. (new) A protective cover assembly as in Claim 34 which  
23        includes manual contact means associated with the frame for  
24        squeezing the frame in a direction generally perpendicular to the  
25        needle to extend the frame and accomplish the needle tip  
26        protection.

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1           36. (new) A protective cover assembly as in Claim 34 wherein  
2       the needle point shield comprises an elongated hollow member having  
3       two end walls with aligned openings through which a needle can  
4       extend when in an operative position; one of the end walls also  
5       having on its interior surface a well that is laterally displaced  
6       from the associated opening, and an interior ridge between the well  
7       and the end wall opening such that when the needle after its use is  
8       retracted through that end wall opening into the interior of the  
9       hollow member the tip of the retracted needle may then be securely  
10      retained within the well and thus protected from re-emerging  
11      outwardly through that end wall opening.

1           37. (new) A protective cover assembly as in Claim 36 wherein  
2       both the end wall opening of the shield and its internal ridge are  
3       laterally displaced from the center of the end wall.

1           38. (new) A needle shield as in Claim 36 wherein the hollow  
2       member has a circumferentially continuous side wall, characterized  
3       in that the member is formed as a unitary molded plastic piece, and  
4       has a lid to form the other end wall thereof which is pivotable  
5       into an operative position and then comes into cork-like engagement  
6       with the side wall of the member.

1           39. (new) A needle shield as in Claim 38 wherein the outer  
2       portion of the opening in the lid is flared outwardly to facilitate  
3       the twisting of the shield relative to the needle.

1           40. (new) The method of protecting the needle tip of a  
2 hypodermic needle after the needle has been used, comprising the  
3 steps of:

4           selecting an elongated needle tip cover having a forward end  
5 wall with a hole therein, and also having a well in the interior  
6 wall surface laterally displaced from the hole, the well and the  
7 hole being separated by a ridge on the interior wall surface;

8           extending the needle through the hole for purpose of use;

9           after the needle has been used, sliding the cover forward  
10 along the needle until the needle tip becomes retracted through the  
11 hole and behind the ridge;

12           moving the cover laterally relative to the needle and  
13 partially withdrawing the cover so that the needle tip becomes  
14 protectively received in the well; and

15           locking the cover in position relative to the needle.

41. The method of Claim 40 wherein the lateral movement of  
the cover is accomplished at least in part by twisting the cover  
relative to the needle.

42 The method of Claim 40 wherein the partial withdrawal of  
the cover is accomplished essentially concurrently with its lateral  
movement.

1           43. (new) The method of protecting the needle tip of a  
2 hypodermic needle after the needle has been used, comprising the  
3 steps of:

4           selecting an elongated needle tip cover having a forward end  
5 wall with a hole therein, and also having a well in the interior  
6 wall surface laterally displaced from the hole, the well and the  
7 hole being separated by a ridge on the interior wall surface;

8           extending the needle through the hole for purpose of use;

9           then after the needle has been used, sliding the cover forward  
10 along the needle until the needle tip becomes retracted through the  
11 hole and behind the ridge;

12           moving the cover laterally relative to the needle and  
13 partially withdrawing the cover so that the needle tip becomes  
14 protectively received in the well; and

15           concurrently locking the cover in position relative to the  
16 needle.

44. The method of Claim 43 wherein the lateral movement of  
the cover is accomplished at least in part by twisting the cover  
relative to the needle.

1           45. (new) A needle point shield comprising:

2           an elongated hollow member having two end walls with aligned  
3           openings through which a needle can extend when in an operative  
4           position; a forward one of the end walls also having on its  
5           interior surface a well that is laterally displaced from the  
6           associated opening, and an interior ridge between the well and the  
7           end wall opening such that when the needle after its use is  
8           retracted through that end wall opening into the interior of the  
9           hollow member the tip of the retracted needle may then be securely  
10           retained within the well and thus protected from re-emerging  
11           outwardly through the end wall opening; wherein the opening in the  
12           rearward one of the end walls provides a pivot support to permit  
13           the shield to twist relative to the needle passing through it, so  
14           that the needle tip then moves laterally from the opening in the  
15           forward end wall into the laterally displaced well.

46. (new) A needle point shield as in Claim 45 which is integrally formed as a single plastic piece.

47. (new) A needle shield as in Claim 46 which further includes an extendible frame pivotally attached to the rearward end wall on the side thereof opposite the laterally displaced opening in the forward end wall, for driving the needle cover forward in order to retract the needle tip within the cover.

48. (new) A needle shield as in Claim 46 wherein the hollow member has a circumferentially continuous side wall, characterized in that the member is formed as a unitary molded plastic piece, and the other end wall thereof is formed as a lid pivotable into its operative position and then comes into cork-like engagement with the side wall of the member.

49. (new) A needle shield as in Claim 48 which further includes a lever arm projecting from the other end of the member and laterally displaced from its associated opening to facilitate applying a twisting force to the needle.

50. (new) A needle shield as in Claim 49 wherein the lever arm is on the side of the member that is opposite the well in the forward end wall.

1           51. (new) A protective cover assembly for a hypodermic needle  
2        having a needle base, a needle shaft, and a needle tip, the  
3        protective assembly comprising:

4           an elongated needle tip cover comprising an elongated hollow  
5        member having forward and rearward end walls with aligned openings  
6        through and beyond which the needle shaft can extend, the forward  
7        end wall also having on its interior surface a well laterally  
8        displaced from the associated opening, and an interior ridge  
9        between the well and the end wall opening such that after use of  
10      the needle when the needle cover is advanced the needle tip may  
11      then be retracted through the forward end wall opening into the  
12      interior of the hollow member and securely retained within the  
13      well;

14           the opening in the rearward one of the end walls providing a  
15      pivot support to permit the shield to twist relative to the needle  
16      passing through it; and

17           a collapsible frame coupled between the needle base and the  
18      needle tip cover and extendible to slide the needle tip cover along  
19      the needle until it protrudes beyond the needle tip;

20           the frame being attached to the rearward end of the cover  
21      member on the side thereof laterally opposite the well in the  
22      forward end wall for twisting the needle tip cover into a position  
23      in which the needle tip is protected by the end wall of the needle  
24      tip cover but is precluded from re-emerging through the opening  
25      therein.

52. (new) A protective cover assembly as in Claim 51 which also includes means for locking the frame in its extended position.

1       53. (new) A needle point shield comprising an elongated hollow  
2 member having on one end thereof an end wall in which there is an  
3 opening through which a needle tip can pass; a lid hingedly  
4 supported from the other end of the hollow member and adapted to  
5 close the other end of the hollow member, the lid having a hole  
6 through which the needle can also pass; and the one end wall also  
7 having on its interior side a well that is laterally displaced from  
8 the opening and an interior ridge between the opening and the well  
9 such that when a needle has first been extended through both the  
10 hole in the lid and the opening in the end wall for purpose of its  
11 use and is then retracted, the tip of the retracted needle can be  
12 securely retained within the well and thus protected from again  
13 re-emerging outwardly through the one end wall opening; the needle  
14 point shield being formed as a unitary molded plastic piece.

54. (new) A needle point shield as in Claim 53 wherein the other end wall thereof is formed as a lid pivotable into its operative position.

1       55. (new) A needle point shield comprising an elongated  
2 hollow member having two end walls with aligned openings, one of  
3 the end walls also having on its interior surface a well that is  
4 laterally displaced from the associated opening, the other end wall  
5 having a lever arm projecting outwardly therefrom but laterally  
6 displaced from its associated opening; whereby when the needle has  
7 been extended in an operative position through both openings and  
8 beyond the one end wall and is then partially retracted into the  
9 hollow member, force may be applied to the lever arm on the other  
10 end wall relative to its associated opening so as to cause the  
11 shield to twist about the needle at that associated opening and the  
12 needle tip to then become lodged within the well in a protected  
13 position.

56. (new) A needle shield as in Claim 55 further characterized in that the member is formed as a unitary molded plastic piece, and the other end wall thereof is formed as a lid pivotable into its operative position.

57. (new) A needle shield as in Claim 55 which further includes an interior ridge between the well and the end wall opening such that when the needle after its use is retracted through that end wall opening into the interior of the hollow member the tip of the retracted needle may then be securely retained within the well and thus protected from again re-emerging outwardly through the end wall opening.

58. (new) A needle shield as in Claim 57 further characterized in that the member is formed as a unitary molded plastic piece, and the other end wall thereof is formed as a lid pivotable into its operative position.

59. (new) A needle shield as in Claim 58 wherein the hollow member has a circumferentially continuous side wall, and the other end wall thereof when in its operative position is in cork-like engagement with the side wall of the member.

60. (new) A needle shield as in Claim 57 wherein the outer end portion of the opening in the other end wall thereof is flared outwardly so as to permit the shield to twist about that opening relative to the needle passing through it.

1       61. (new) A needle protective assembly comprising a needle tip  
2       cover having an end wall with an opening through which the needle  
3       shaft may protrude, and an extendible frame integrally formed with  
4       the cover, the frame being operable when it is extended to advance  
5       the cover along the needle shaft and also to apply a twisting force  
6       to the cover until the needle tip is retracted within the cover and  
7       moved laterally within it to a protected position; the frame also  
8       being movable beyond a fully extended position and having means for  
9       then locking it into engagement with the shaft of the needle.

REMARKS

There is no present litigation regarding the issued patent and there has been none before this date. This application has no requested changes in original drawings. This application has no requested changes in original specifications. This application has no requested changes in original claims. All original claims are being resubmitted and none are being canceled. New claims 23 through 61 are being submitted. All new claims are clearly supported by the original drawings.

New claims 23 - 27 essentially constitute alternative and more encompassing methods of claiming those aspects of the invention that were previously claimed in claims 1 - 22, and for foundation rest upon the same disclosure. Claims 28 - 32 address newly identified aspects of the invention, for which the necessary foundation in each case is set forth below.

New claims 28 - 32 fall into two classes, the first class (1) being those which claim the combination of (a) the hypodermic syringe and needle; (b) the needle point guard safety cap assembly; and (c) a protective sheath, since it is that combination that is pre-assembled and packaged for shipment; and the second class (2) relating to the hingedly interconnected aspect of the invention, that structure permitting a rotational method of fabrication that avoids any need for any inwardly directed movement of the fingers along the axis of the needle in the direction of the needle tip.

In the specification at Col. 3, lines 10 - 16, it is noted that

The needle point cover is typically adapted to receive a typical needle sheath. As such, the needle point guard safety cap assembly typically can be installed prior to sheath installation and needle distribution. Needles can therefore be distributed with the needle point cover stowed distal the point and with the sheath covering the needle in the normal fashion.

Such recitation provides foundation for new claim 28, which likewise places the needle point cover "distal the point" (i.e., proximal to the syringe), and then the sheath distal to the needle point cover. That a combination of the syringe, a needle, and the needle point guard safety cap assembly are contemplated as a composite unit (i.e., the "needle-protected hypodermic syringe" of claim 28) is shown by the language at Col. 3, second last line, to Col. 4, line 1: "The present invention is designed to be installed prior to needle use. It typically would be installed on the needle or syringe prior to distribution." One error in the initial filing and prosecution of

this '397 patent was thus the failure to recognize that "the invention" actually encompassed that composite, and not merely the needle point guard safety cap assembly taken by itself. The additional recitations of claim 29 essentially replicate elements previously claimed, and for which adequate foundation was found in the prosecution and allowance of the set of claims in the issued patent.

The rotational assembly of the "needle-protected hypodermic syringe" of claim 28, such assembly being noted in claims 30 - 32, is described at Col. 4, lines 4 - as follows:

To install the presently preferred embodiment of the needle point guard safety cap assembly, the syringe attachment member and the needle point cover must be rotated into position to receive the needle. The syringe attachment member and frame are flexibly coupled. The syringe attachment member or base cup **150** is therefore rotated approximately 90 degrees with respect to the frame **130** so that the needle can extend through the syringe attachment member **150** approximately parallel to the extended frame **130**.

As equivalently described from an opposite perspective, and perhaps giving a better picture of the steps that actually occur, one can say that when the base cup **150** has been placed onto the needle hub or syringe -- ". . . the needle point guard safety cap assembly **100** is adapted to be attached to the needle hub or syringe." (Col. 5, lines 26 - 28) — the frame **130**, which as shown in Figs. 1 and 2 is initially disposed at an angle of 90 degrees to base cup **150**, is rotated 90 degrees so as to become in alignment with base cup **150** and thus in alignment with the needle which can then pass therethrough. The specification text just quoted thus provides foundation for the recitations of claim 30 wherein the proximal end segment is rotated into a disposition that is colinear with said hypodermic needle, and of claim 32 with respect to the "rotational means" by which the composite as a whole is constructed. Foundation for the analogous process of bringing the needle point cover member into alignment with the needle, as recited in claim 31, is as follows (Col. 4, lines 13 - 15):

Next, a lid or enclosing member **118**, which is flexibly coupled to the needle point cover **110**, is rotated to plug or enclose the cover **110**.

These last two text recitations, respectively addressing the rotation of frame **130** (with its cover **110**) into alignment with base cup **150**, and then the rotation of the lid or enclosing member **118** into alignment with cover **110**, also provide the foundation for claim 33 that recites the rotational method of assembly of the needle-protected hypodermic syringe of claim 28.

New claims 34 through 60 relate mainly to the needle point cover as a subcombination.

It should be noted that in the original application serial No. 09/160,511 the original claims 12 and 13 were rejected on the patents to Jenkins, Hagen and Steyn. Original claims 12 and 13 were subsequently canceled from that application. It is nevertheless believed that the needle point cover has many aspects that are patentable over the prior art.

New claim 61 broadly covers the overall needle protective assembly but is believed to distinguish over the prior art by virtue of the mechanism for locking the extendable frame to the needle shaft.

Favorable action is solicited.

Respectfully submitted,

January 17,  
2002



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